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RUEHBU/AMEMBASSY BUENOS AIRES 2489  
RUEHME/AMEMBASSY MEXICO 3399  
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DEPT FOR WHA/AND, EB/IPE SWILSON  
COMMERCE FOR 4331/MAC/WH/MCAMERON  
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SUBJECT: PFIZER WINS IPR CASE

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¶1. (SBU) Summary. Pfizer, in 2002, filed a patent infringement case against Indian company Ranbaxy, alleging that the company was illegally copying its Lipitor patent. Indecopi, (Peru's IPR Administrator), issued two final decisions in June in favor of Pfizer, finding Ranbaxy guilty of violating Pfizer's patents and denying the Indian company's request for nullification of the Pfizer patent. With this action, Ranbaxy can no longer sell its copy of Lipitor on the Peruvian market, although it retains the right to sell other medicines. The Indian company must also pay a fine of \$8,500 to Indecopi. Although Pfizer is pleased with the outcome, the case shows Indecopi's inherent deficiencies in protecting intellectual property rights. Post will continue to monitor the case in light of Indecopi's history of uneven enforcement actions. End Summary.

Lipitor Patent Copied  
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¶2. In 2002, Pfizer, one of the ten pharmaceutical companies to hold patents in Peru, filed a patent infringement case against Indian company Ranbaxy, alleging that the company was copying its patent for Lipitor, also known as atorvastatin calcium. (Note: Lipitor, used to control cholesterol levels, is one of Pfizer's most successful drugs. End Note.) Several months after Pfizer filed its complaint, Indecopi, Peru's IPR Administrator, issued a precautionary measure against Ranbaxy based on possible patent infringement. The precautionary measure prohibited Ranbaxy from selling the product in Peruvian markets, although it could continue producing the drug. After 120 days, per Peruvian law, the precautionary measure expired, allowing Ranbaxy to resume selling its product in the Peruvian market.

Indecopi Fails to Act  
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¶3. (SBU) During the past four years, Pfizer officials met frequently with Indecopi officials, who continued to drag their feet on the issue. In 2003, per Indecopi's request, Ranbaxy presented Indecopi with confidential test data to prove that its drug was not a copy of Pfizer's patent. In addition to the information, Ranbaxy argued that Lipitor is patented to treat cholesterol problems; Ranbaxy's drug instead sought to counter the effects of erectile dysfunction, with the side effect of lowering cholesterol.

¶4. (SBU) As a result of Ranbaxy's actions, the Director of Indecopi's patent office informed Pfizer that the company needed to prove that Ranbaxy's drug was a pirated copy. Pfizer, noting that this practice appeared to be a violation of TRIPS, submitted information to Indecopi. After a year of reviewing the case, Indecopi ruled in favor of Ranbaxy, stating that the Indian company's drug, while similar to the Lipitor patent, was created through a different chemical process. Ranbaxy then petitioned Indecopi to nullify Pfizer's Lipitor patent.

#### Pfizer Appeals and Wins Both Cases

¶5. (SBU) Pfizer immediately appealed both Indecopi's decision and Ranbaxy's request for patent nullification, providing Indecopi additional test data information. In December 2005, Indecopi issued resolution 1468-2005, overturning its previous decision on the Ranbaxy drug. After reviewing the case, Indecopi found that both products were crystalline and shared the same spectrum characteristics. Indecopi concluded that the Ranbaxy drug violated Pfizer's patent and dismissed the company's nullification request.

¶6. (SBU) Ranbaxy appealed both of Indecopi's decisions, but on June 1, 2006, Indecopi, with resolution 692-2006, dismissed Ranbaxy's nullification request, upholding the 2005 resolution in favor of Pfizer. Indecopi's decision is final, although Ranbaxy can file a petition for judicial review within three months of the resolution (by September 1, 2006).

¶7. (SBU) On June 6, Indecopi issued an additional resolution, 729/2006, which found that Ranbaxy infringed on Pfizer's patent rights when marketing its drug in Peru. Per the decision, Ranbaxy immediately halted the sale of this product, although it can sell its other drugs on the market. Ranbaxy must pay a fine of \$8,500 to Indecopi to cover the costs of the hearings.

#### Comment

¶8. (SBU) While Pfizer is pleased with Indecopi's final decision, the patent infringement case lasted four years, costing the company more than \$5 million in sales. Two other U.S. pharmaceutical firms continue to face similar problems and await Indecopi action. This case highlights the inefficiency of Indecopi's procedures and inability to protect pharmaceutical patents. Indecopi officials recognize that there are flaws in the system and hope that the next Administration changes the process. Post expects that Indecopi will request substantial technical assistance during the implementation of the FTA, in order to close loopholes, promote capacity building and improve its legal framework. We are working with State, Commerce, U.S. Patent and Trade, and U.S. Customs to provide additional training when funding becomes available.

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